



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

OCT 31 2000

Rec'd
NOV 15 2000
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Mr. David Stewart
Label Regulations
Young Living Essential Oils
250 So. Main Street
Payson, Utah 84651

Dear Mr. Stewart:

This is in response to your letter of October 25, 2000 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)).

Although you submitted your letter to FDA as the notification required by 21 U.S.C. 343(r)(6) and 21 CFR 101.93(a), it is not signed. Therefore, the notice does not meet the requirement in 21 CFR 101.93(a)(3) that it be signed by a responsible individual or the person who can certify the accuracy of the information presented and contained in the notice. Since your notice was not submitted in accordance with the requirements of 21 U.S.C. 343(r)(6) and 21 CFR 101.93(a), it does not satisfy the statutory requirement to enable a dietary supplement to bear a claim under 21 U.S.C. 343(r)(6) on its label and labeling. If you intend to make a claim for your product pursuant to 21 U.S.C. 343(r)(6), you must provide the notification required by that section in accordance with 21 CFR 101.93(a) and it must be signed.

Please contact us if we may be of further assistance.

Sincerely,

Robert J. Moore, Ph.D.
Chief, Dietary Supplements Branch
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling,
and Dietary Supplements

978-0163

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Young Living ESSENTIAL OILS™

October 25, 2000

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
200 C. Street S.W.
Washington, D.C. 20204

Re: Notification for Statements on Dietary Supplement Labeling

Dear Sir/Madam:

This notification is being submitted on behalf of Young Living Essential Oils, Payson, Utah, a distributor of dietary supplement products (hereafter "Young Living").

Pursuant to the requirements of Section 6 of the Dietary Supplement Health and Education Act of 1994, 21 U.S.C. § 343 (r) (6), and in accordance with the authorized provisions of 21 CFR § 101.93 (a), your Agency is hereby notified that Young Living proposes to make and/or has made statements of "nutritional support", as described in 21 U.S.C. § 343 (r) (6) (A), for its dietary supplements as follows:

<u>Product Name</u>	<u>Statement(s)</u>
AD&E	A powerful antioxidant formula that supports healthy heart and immune function
Arthro Plus	Supports normal joint function
Arthro Tune	A powerful herbal complex that supports healthy joint function
AuraLight	A fast-acting St. John's Wort mouth spray that helps to reduce stress and create a relaxed, calm feeling
Be-Fit	Supports normal muscle formation Helps maintain immune function
CardiaCare	Nutritionally supports the heart and cardiovascular system
Chelex	Supports healthy immune function
ComforTone	High-powered herbal formula that supports normal digestive and colon function
Essential Omegas	Supports normal cardiovascular function
Exodus	Supports healthy immune function
HRT	Provides nutritional support for the heart
ImmuGel	Supports healthy immune function
ImmuneTune	Supports normal immune and pancreatic function
JuvaTone	Promotes healthy liver function
K&B	Supports healthy kidney and bladder function

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